
OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

TECHNICAL SECTION COMPLETE LETTERS

I. PURPOSE OF GUIDE

This guide establishes standardized language to assure uniformity of the technical section complete letters. Technical Section Complete Letters are only issued under an Investigational New Animal Drug (INAD) file.

II. EXAMPLE FORMAT: TECHNICAL SECTION COMPLETE LETTER

NOTE: In the following paragraphs, any wording in italics requires the preparer to add information. Wording in the examples that is not italicized is boilerplate language and should not be modified in any way.

A. INTRODUCTORY PARAGRAPH:

By letter dated <*date*>, you submitted/requested <*complete description of submission/request*> to the Investigational New Animal Drug (INAD) file <*INAD number*> for <*drug product.*> The drug is proposed as a <*pharmacological action, if available; e.g., growth promotant, diuretic, dermatologic, analgesic, abortifacient,*> in <*species/class.*> The submission submitted/requested <*complete description of submission/request.*>

B. TECHNICAL SECTION COMPLETE PARAGRAPHS:

Based on the information in this submission and the information contained in *<list all relevant files,>* the Division of *<name>* considers the *<technical section name>* technical section to be complete. *<Insert relevant Standard Division Boilerplate paragraphs for technical section complete letters.>*
<Discuss relevant technical section information here.>

A final decision on whether the application can be approved will be made when all the data for all technical sections submitted as part of an Administrative NADA, NADA, or supplemental NADA are viewed as a whole and it is determined that:

1) the information contained in and referenced by the application supports approval;

2) the GMP status of each manufacturing facility is current and satisfactory;

3) if a claim for categorical exclusion was made, conditions for the categorical exclusion are still applicable.

4) there is no new information that would preclude the approval of the application.

C. LANGUAGE FOR CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC):

Manufacturing process validation provides assurance that the manufacturing processes will reliably meet predetermined specifications. Manufacturing process validation is demonstrated by documentation that the manufacturing processes are adequate to preserve the identity, strength, quality, and purity of the new animal drug.

Manufacturing process validation does not need to be completed prior to approval. However, because a new animal drug is adulterated if it does not conform to current good manufacturing practice (21 USC 351(a)(1)(B)) and

current good manufacturing practices require validation of manufacturing processes for finished pharmaceuticals (21 CFR 211) and Type A Medicated Articles (21 CFR 226), it must be complete before a product is shipped.

If the manufacturing process validation information is available for evaluation before approval, the FDA District Office may inspect it and determine if it is acceptable. If the information is not available for evaluation before approval, or process validation deficiencies were noted by the FDA Investigator during the pre-approval inspection, you should contact the appropriate FDA District Office after the manufacturing process validation has been completed and prior to shipping the drug product. This will give the FDA District Office an opportunity to inspect and verify the validation of the manufacturing process.

If you ship a drug product prior to completion of the validation process, FDA may take regulatory action, such as seizing the product.

<Additional transmittal comments>

An expiration date of <*XX*> months is acceptable for this product.

D. LANGUAGE FOR ENVIRONMENTAL TECHNICAL SECTION:

Please refer to Guide 1243.7220 for standardized language for the environmental technical section complete letter.

E. CLOSING PARAGRAPHS OF THE LETTER:

Future correspondence regarding your submission to the Investigational New Animal Drug file should include the date of this correspondence and our file number, INAD xxx-xxx <*submission code.*> A copy of this technical section complete letter should be included in the Administrative NADA.

If you need further information regarding this letter, please contact <*name,*> who may be reached at <*telephone number.*>

Sincerely yours,
Signature block of Division Director

cc: HFV-199 INAD <*INAD number, submission code xxxx*>[salmon copy]

<*list additional copies*>

III. REFERENCES

Federal Food, Drug, and Cosmetic Act, section 512(j)

"Phased Review Policy" in Center for Veterinary Medicine Document and Submission Information – An Update April 1995, revised November 1995 Handout at AHI Conference

Program Policy & Procedure Manual Guide 1243.7220, Environmental Review: Evaluating Claims of Categorical Exclusion for Actions Relating to New Animal Drugs http://www.fda.gov/cvm/index/policy_proced/ppindex.html